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IN THE

Supreme Court of the United States

LABORATORY CORPORATION OF AMERICA HOLDINGS
(doing business as LabCorp),

Petitioner,

v.

METABOLITE LABORATORIES, INC. and
COMPETITIVE TECHNOLOGIES, INC.,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

AMICUS CURIAE BRIEF OF THE FEDERAL CIRCUIT BAR ASSOCIATION IN SUPPORT OF RESPONDENTS

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Lab. Corp. v. Metabolite Labs, 125 S. Ct. 1413, 161 L. Ed. 2d 188 (2005) 7

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State Street Bank & Trust Co. v. Signature Financial Group, 149 F.3d 1368 (Fed. Cir. 1998) .....*passim*

Taylor v. Freeland & Kronz, 503 U.S. 638 (1992) 8

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FEDERAL STATUTES

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Jay Dratler, Jr., Article: *Alice in Wonderland Meets the U.S. Patent System*, 38 AKRON L. REV. 299 (2005) 17, 19

Robert M. Hunt, Article: *You Can Patent That? Are Patents on Computer Programs and Business methods Good for the Economy?*, BUSINESS REVIEW Q1 (Federal Reserve Bank of Philadelphia 2001) 17

LAROUSSE DICTIONARY OF SCIENCE AND TECHNOLOGY 64 (Peter M.B. Walker ed., 1995) 10

Gerald J. Mossinghoff, Article, *Remedies Under Patents on Medical and Surgical Procedures*, 78 J. PATENT & TRADEMARK OFFICE SOC. 789 n. 17 (1996) 16

Cited Authorities

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Judge Pauline Newman, Foreword: *The Federal Circuit in Perspective*, 54 AM. U. L. REV. 821 (2005) 12

Chief Justice Rehnquist, *Seen In a Glass Darkly: The Future of the Federal Courts*, 1993 WISC. L. REV., Vol. 1 (1993) 4-5

John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U. L. REV. 771 (2003) 15

To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, a Report by the Federal Trade Commission (October 2003) 18

USPTO White Paper on Automated Financial or Management Data Processing Methods (Business Methods) (2001) 18

Allen Clark Zoracki, Comment: *When is an Algorithm Invented? The Need for a New Paradigm for Evaluating an Algorithm for Intellectual Property Protection*, 15 ALB. L. J. SCI. & TECH. 579 (2005) 14

STATEMENT OF INTEREST OF AMICUS CURIAE

The Federal Circuit Bar Association ("FCBA") is a national organization comprising approximately 2,400 attorneys whose practice concerns the United States Court of Appeals for the Federal Circuit in all aspects of its jurisdiction. The FCBA offers a forum for common concerns and dialogue between the bar and the judges of the Federal Circuit. One purpose of the FCBA is to offer assistance and advice to the Federal Courts, including briefs *amicus curiae*, on matters affecting practice before the Federal Circuit and the law within its exclusive jurisdiction.[1]

Pursuant to Supreme Court Rule 37.2(a), the FCBA has conferred with the parties regarding the filing of this brief *amicus curiae*, and both have consented to its filing. Written evidence of their consent has been filed separately.

Although the FCBA offers this brief in support of the Respondents, it takes no position as to the validity of Claim 13 of U.S. Patent No. 4,940,658 ("the '658 patent"). The FCBA respectfully submits that the Court should dismiss the petition for certiorari as improvidently granted. The only issue even arguably appropriate for certiorari jurisdiction relates to the possible invalidity of Claim 13 for want of patentable subject matter. That issue was not litigated in the lower courts, and this Court should decline to decide the issue on an incomplete record. If, however, the Court chooses to decide the issue of patentable subject matter, the FCBA

1. Pursuant to Supreme Court Rule 37.6, the FCBA represents that no counsel for a party authored this brief in whole or in part. No person or entity, other than the *amicus curiae*, its members, or its counsel, made any monetary contribution to the preparation or submission of the brief.

strongly urges the Court to confine its holdings to the particular facts of this case and in such a way as not to alter existing law. Any broader ruling from this Court on the issue of patentable subject matter could inadvertently disturb the settled and reasonable expectations of those engaged in technology-based industries.

SUMMARY OF ARGUMENT

1. The petition for certiorari should be dismissed as improvidently granted. This Court enjoys discretion to enter such an order, dismissals of this kind often being ordered *sua sponte*. The Court should recognize that the question accepted for certiorari review poses quite discrete issues. Petitioner suggests, initially, that Claim 13 of the '658 patent is invalid as "indefinite, undescribed, and non-enabling": separate issues relating to invalidity under 35 U.S.C. § 112. It then goes on to suggest that Claim 13 also presents an issue of patentable subject matter under § 101. The § 112 issues were litigated in the lower courts; the § 101 issue was not. Petitioner's conflation of these distinct legal issues obscures this important fact. This Court should not depart from its salutary general practice of declining to address issues that were not presented to the courts below.

Moreover, this case does not present a proper record for resolution of the patentable subject matter issue. Claim 13 might well have been construed differently by the lower courts had the issue been raised. Claim construction was litigated vigorously below, with both parties offering widely different interpretations of its scope. The Federal Circuit's eventual opinion evoked a strongly worded dissent on the claim construction issue. The panel majority's claim interpretation is final and unreviewable. This Court enjoys

little or no assurance that any ruling it makes with respect to the § 101 issue will be premised on an accurate claim interpretation.

2. If the Court is inclined to decide the issue of patentable subject matter, the FCBA urges the Court to confine its holdings to the facts of this case and not to alter existing law. For the past quarter-century, reliance on this Court's decision in *Diamond v. Diehr*, 450 U.S. 175 (1981) and the cases therein cited has been widespread and substantial. Consistently with *Diehr* and its predecessors, lower courts have repeatedly ruled that few exceptions exist to the broad categories of patentable subject matter listed in § 101. Extensive Federal Circuit jurisprudence in this area confirms the Congressional judgment that broadly patentable subject matter fosters innovation in technology-based industries such as computer software, pharmaceuticals, and biotechnology, where subject matter is often unpredictable. Nor, during the twenty-five years that have passed since *Diehr*, has Congress seen fit to limit the scope of § 101, even in the wake of decisions confirming the patentability of ever more diverse subject matter. Rather than limiting the potential scope of patents, Congress, when it has seen fit to act, has exempted certain actions or actors from charges of infringement. Statutory exceptions to infringement liability serve as a practical alternative to limiting the categories of subject matter eligible for patent.

Recognizing broadly patentable subject matter does not automatically confer monopoly status. Patent protection remains expressly conditioned upon the other statutory requirements for patentability, including §§ 102, 103 and 112. Restricting the scope of patentable subject matter is not an appropriate means for controlling what some perceive as

improvidently granted patents involving methods of doing business, methods of practicing medicine, diagnostic methods, and the like. In fact, rigorous examination of applications for business method patents has resulted in surprisingly few issued patents relative to the number of filings. This fact confirms that the United States Patent and Trademark Office ("USPTO") is capable of responding adequately to increased filings in an area of newly recognized subject matter.

ARGUMENT

I. The Court Should Dismiss the Petition as Improvidently Granted

A. Historical Background of Certiorari Jurisdiction

The creation of discretionary certiorari jurisdiction over a century ago permitted the Court to control its docket and thus to focus on legal issues of national importance. Justice Frankfurter observed that replacing mandatory jurisdiction with discretionary jurisdiction was necessary if "the proper discharge of the Court's indispensable functions were to be rendered feasible." *Dick v. New York Life Insurance Co.*, 359 U.S. 437, 459 (1959) (Frankfurter, J. dissenting). Discretionary jurisdiction "was not conferred upon this Court merely to give the defeated party in the Circuit Court of Appeals another hearing." *Magnum Co. v. Coty*, 262 U.S. 159, 163 (1923). Today nearly all Supreme Court cases are heard through a discretionary writ of certiorari. Certiorari jurisdiction transformed the Supreme Court "from an error-correcting Court of general appellate jurisdiction to a Court whose special concerns are constitutional interpretation and significant questions of federal law." Chief Justice Rehnquist,

Seen In a Glass Darkly: The Future of the Federal Courts, 1993 WISC. L. REV., Vol. 1, 11 (1993).

The Supreme Court's "indispensable functions" are carried out through careful scrutiny of each petition according to established rules. Supreme Court Rule 10 recites long-held generalizations thought relevant to proper exercise of certiorari jurisdiction. *See Hubbard v. United States*, 514 U.S. 695, 720 (1995) (Rehnquist, C.J. dissenting). Rule 10 warns from the outset that the Court's judicial discretion will be exercised "only for compelling reasons," and adds that "certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law." The word "important" appears in several places throughout Rule 10, emphasizing that certiorari will not be granted for merely interesting issues. Certiorari jurisdiction is generally confined to importance "beyond the academic or the episodic." *Rice v. Sioux City Cemetery*, 349 U.S. 70, 74 (1955). Even "serious legal questions" may not be sufficiently important for certiorari jurisdiction. *English v. Cunningham*, 361 U.S. 905, 907 (1959). The concept of "importance" relates to the importance of the issues "to the public as distinguished from that of the parties." *Layne & Bowler Corp. v. Western Well Works*, 261 U.S. 387, 393 (1923).

B. The Only Important Issue Presented for Review Relates to Patentable Subject Matter, and This Issue Is Not Reviewable on the Record Below

This Court granted certiorari on the following question:

> Whether a method patent setting forth an indefinite, undescribed, and non-enabling step

> directing a party simply to "correlat[e]" test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that a doctor necessarily infringes the patent merely by thinking about the relationship after looking at the test result.

(Petition for Certiorari at pp. (i)). Petitioner's question assumes *a priori* that the method at issue includes a step that is "indefinite, undescribed, and non-enabling," three separate and distinct bases for invalidity under § 112. It then suggests that because the claim at issue merely describes "a basic scientific relationship," it cannot be validly patented. This conclusion, if accurate, necessarily implicates § 101. Although introduced through an apparent invocation of § 112, petitioner's question does not suggest any "important" § 112 issue, *i.e.*, one with ramifications extending beyond the facts of this particular case. Indeed, the legal standards codified in § 112 do not invite inquiry into whether a patentee can "validly claim a monopoly over a basic scientific relationship"; rather, they are concerned only with evaluating the adequacy of the patentee's disclosure.

Section 112, ¶ 1 requires a patent applicant to provide a

> written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The second paragraph of § 112 requires the specification to conclude with one or more claims "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." Section 112 simply does not concern itself with the issue petitioner is actually asking this Court to resolve: whether Claim 13 is inherently unpatentable because it broadly claims the right to exclude others from "thinking" about "a basic scientific relationship." This is an issue that arises, if at all, under § 101. Put another way: even if one accepts that, as Claim 13 was construed by the majority opinion below, "a doctor necessarily infringes the patent merely by thinking about the relationship after looking at the test result," the claim is not therefore "indefinite, undescribed, and non-enabling." On the contrary, logic suggests that only definite, enabled, and described claims could be so easily infringed. In sum, the question as to which certiorari was granted does not raise, either explicitly or implicitly, any "important" issue under § 112.

The petitioner's question does, however, suggest an issue relating to the scope of patentable subject matter under § 101: whether Claim 13 of the '658 Patent is invalid because one cannot patent "laws of nature, natural phenomena, and abstract ideas." *Diehr*, 450 at 185. Indeed, this Court presented the subject matter question to the Solicitor General. *Lab. Corp. v. Metabolite Labs*, 125 S. Ct. 1413, 161 L. Ed. 2d 188 (2005). Declining to offer a definitive answer, the Solicitor General noted that the record on patentable subject matter was not sufficiently developed, and urged the Court to deny certiorari. In support of its position, the Solicitor General cited *Adarand Constructors, Inc. v. Mineta*, 534 U.S. 103, 109 (2001), and *Glover v. United States*, 531 U.S. 198, 205 (2001), two cases stating the general rule that certiorari jurisdiction is normally denied

when the record is unclear and where, as here, the issue for review was also not presented below.

After certiorari was granted in *Adarand*, it became clear that the petitioner was seeking review of a question that had not been directly litigated in the lower court. 534 U.S. at 108. In dismissing the writ, the Court stated "[w]e ordinarily 'do not decide in the first instance issues not decided below.'" (quoting *NCAA v. Smith*, 525 U.S. 459, 470 (1999)). As the Court explained in *Glover v. United States* (citing *Taylor v. Freeland & Kronz*, 503 U.S. 638, 646 (1992)), this rule applies even when certiorari is properly granted on other issues. "In the ordinary course we do not decide questions neither raised nor resolved below." 531 U.S. at 205.

Even assuming that the § 101 subject matter issue is "fairly included" in the petition in compliance with Supreme Court Rule 14.1(a),[2] the Court should decline to decide the

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2. The *Glover* court went on to state that "[a]s a general rule, furthermore, we do not decide issues outside the questions presented by the petition for certiorari." 531 U.S. at 205. (citing Supreme Court Rule 14.1(a)). Supreme Court Rule 14.1(a) states, "[o]nly the questions set out in the petition, or fairly included therein, will be considered by the Court." It is doubtful that the subject matter issue is "fairly included" in the current petition under consideration. Issues of invalidity under § 112 are legally distinct from an issue of patentable subject matter under § 101. Petitioner fails even to cite § 101 as a basis for invalidity in its petition. The petition sets forth arguments traditionally heard during a challenge to patentable subject matter under § 101, but it is unclear that these arguments, framed in terms of § 112, are sufficient to comply with Rule 14. This Court's decisions suggest that strict compliance with Rule 14 is required, refusing on more than one occasion to address issues not "fairly included" in a petition. *See, e.g., Thornton v. United States*, 541 U.S.

(Cont'd)

issue. The proper scope of Claim 13 was hotly disputed by the parties below; indeed, as the dissent below illustrates, even the panel that decided the case could not reach agreement on the proper construction of that claim. *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1372 (Fed. Cir. 2004) (Schall, J., dissenting). Patentability under § 101 depends directly upon a proper claim construction. *State Street Bank & Trust Co. v. Signature Financial Group*, 149 F.3d 1368, 1370 (Fed. Cir. 1998) ("Whether the . . . patent is invalid for failure to claim statutory subject matter under § 101, is a matter of both claim construction and statutory construction."). Here, the claim construction adopted by the trial and appellate courts might well have been different had the § 101 issue been raised. For example, the "assay" limitation of Claim 13 could have been construed in such a manner as to avoid the issue that petitioner now asserts. *See, e.g., Liebel Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 911 (Fed. Cir. 2004) (reciting general rule that "claims should be so construed, if possible, as to sustain their validity.").

Here, the lower court did not interpret the "assay" limitation of Claim 13. Had it considered a challenge to the subject matter of Claim 13, the "assay" limitation could have been limited to a step involving "[t]ransformation and reduction of an article 'to a different state or thing.'" *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972). Transformation or reduction of an article to a "different state or thing" has long served as a key sign that a method claim is drawn to

(Cont'd)

615, 624 (2004); *Jones v. United States*, 527 U.S. 373, 394 n.11 (1999); *Phillips v. Wash. Legal Found.*, 524 U.S. 156, 184 n.4 (1998) (reasoning that "it would be improper for us *sua sponte* to raise and address the question. . . .").

patentable subject matter. *Diehr*, 450 U.S. 184 (quoting *Benson*, 409 U.S. at 70; *see also Parker v. Flook*, 437 U.S. 584, 588-589 & n.9 (1978); *Cochrane v. Deener*, 94 U.S. 780, 787-788 (1876)). The Solicitor General rightly notes that the term "assay" is generally understood to refer to "[t]he quantitative analysis of a substance to determine the proportion of some valuable or potent constituent ." (Br. of the Sol. Gen. at p. 9, citing LAROUSSE DICTIONARY OF SCIENCE AND TECHNOLOGY 64 (Peter M.B. Walker ed., 1995)). This definition implies a transformation of matter, however, the factual record in this case is not adequately developed on this point. It is at least possible that other methods of measuring total homocysteine levels would not involve a transformation of matter.

The importance of claim construction to proper resolution of the patentable subject matter issue cannot be overemphasized — but claim construction is not before this Court. The Court has explained that prior to engaging in a § 101 subject matter inquiry, the Court should determine "what type of discovery is sought to be patented." *Flook*, 437 U.S. at 593. "In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole." *Diehr*, 450 U.S. at 188; *Flook*, 437 U.S. at 594 & n.16. Here, the limitations of Claim 13 were never considered by the courts below or by the parties in the context of a subject matter challenge. As previously noted, claim construction presented a close issue, as to which one of the three panel members dissented. *See Metabolite Labs.*, 370 F.3d at 1372 (Schall, J., dissenting). Petitioner's failure to raise the patentable subject matter issue below deprived the courts and Respondents of an opportunity to address claim construction in light of § 101. It also means that this Court is, in effect,

"stuck" with a claim construction ruling that could be inaccurate or that was, at the very least, not fully considered in light of an adequately developed factual record. In this context, the Court should decline to address the § 101 issue.

In numerous similar cases, this Court has dismissed the petition as improvidently granted. *Wainwright v. City of New Orleans*, 392 U.S. 598, 599 (1968) (dismissing petition because record was "too opaque" and "too sketchy"); *see also, Kimbrough v. United States*, 364 U.S. 661 (1961) (dismissing petition because the question was not "presented with sufficient clarity in this case"); *Mitchell v. Oregon Frozen Foods Co.*, 361 U.S. 231 (1960) (dismissing petition because "ambiguities in the record as to the issues sought to be tendered" appeared); *Rogers v. United States*, 522 U.S. 252, 258-59 (1998) (same); *McCarthy v. Bruner*, 323 U.S. 673 (1944) (same). In one such case, Justice Frankfurter explained:

> [c]onsidering the volume of cases which invoke the Court's discretionary jurisdiction — as of today 1,091 such cases have been passed on during this Term[3] — it would be indeed surprising if in each Term there were not two or three instances of petitions which, after passing through the preliminary sifting process, did not survive the scrutiny of oral argument.

Needelman v. United States, 362 U.S. 600, 601 (1960). The Court should make a similar determination here.

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3. According to the Supreme Court's Public Information Office, more than eight times as many cases were considered during the October Term 2004 (8,588), and the Court has already considered over five times as many this Term (5,654 and counting).

II. Any Decision of the Court on the Issue of Patentable Subject Matter Should be Confined to the Facts of This Case and Should Not Alter Existing Law

If, notwithstanding the considerations discussed above, the Court elects to decide the belatedly raised issue of patentable subject matter, the FCBA respectfully urges the Court to confine both its holding and any dicta to the facts of this case, and to ensure that its ruling does not extend beyond prior precedent in this area. Any broader ruling by this Court on the scope of patentable subject matter could inadvertently disturb well-settled and entirely reasonable expectations held by those engaged in technology-based industries.

A. Historical Development of Federal Circuit Subject Matter Jurisprudence

Shortly after this Court's decision in *Diehr*, the United States embarked on a "juridical experiment" by establishing the Federal Circuit Court of Appeals, "the only major change in federal court structure in a hundred years." Judge Pauline Newman, Foreword: *The Federal Circuit in Perspective*, 54 AM. U. L. REV. 821 (2005). At a time when it was widely believed that a "diminished capability of patents to support investment in new or improved products contributed to the weakness of the economy," creation of the Federal Circuit was intended to "reinvigorate the nation's industrial strength and technological leadership, with the assistance of a revived and effective patent system." *Id.* at 822. "It was recognized then, as now, that our economic strength as a nation depends on technologic leadership, the balance of trade, and a culture that favors creativity, entrepreneurship, and industrial activity. These aspects can be fostered or deterred by governmental policy." *Id.* at 821.

This Court's decision in *Diehr* and its predecessors laid the legal foundation upon which the Federal Circuit has consistently reinforced the view that there are very few exceptions to the broad categories of patentable subject matter listed in § 101. "We have come a long way from the days when judges frowned on patents as pernicious monopolies deserving scant regard. Today, patents are the backbone of much of the national economy, and, as this court has recently held, virtually anything is patentable." *Hughes Aircraft Co. v. United States*, 148 F.3d 1384, 1385 (Fed. Cir. 1998) (citing *State Street*, 149 F.3d at 1368). The last twenty-five years have seen rapid innovation in newly-emerging fields, especially in computer software and biotechnology. The U.S. patent system has repeatedly adapted to and in most cases, embraced new technologies.

In 1994, the Federal Circuit decided *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994), a case widely credited with encouraging the USPTO's current approach to software patent applications. Elaborating on the principles set out in *Diehr*, the Federal Circuit commented that:

> the proper inquiry in dealing with the so called mathematical subject matter exception to § 101 alleged herein is to see whether the claimed subject matter as a whole is a disembodied mathematical concept, whether categorized as a mathematical formula, mathematical equation, mathematical algorithm, or the like, which in essence represents nothing more than a "law of nature," "natural phenomenon," or "abstract idea." If so, *Diehr* precludes the patenting of that subject matter. That is not the case here.

Id. at 1544. *Alappat* set the stage for a wealth of innovation over the next decade in the fields of software and Internet communications.[4] Four years after *Alappat*, the Federal Circuit decided *State Street*, 149 F.3d at 1370, eliminating pre-existing confusion over the patentability of business methods. Since *State Street*, the USPTO has issued hundreds of patents on inventions drawn to methods of doing business.[5]

B. There is No Compelling Reason to Change the Current Law on Patentable Subject Matter

Any decision from this Court disturbing its own prior precedent or the view of § 101 currently held by the Federal Circuit and the USPTO would call into question a substantial number of patent claims and disrupt reliance on the patent system by numerous technology-based companies. As noted by the Solicitor General,

> The number of patent claims that would be invalidated by a reversal of the Federal Circuit's understanding of *Flook* and *Diehr* is difficult to predict, and would depend in part on the rule of law adopted by this Court. At a minimum,

4. According to some estimates, computer software and Internet patents represent more than fifteen percent of all patents currently issued by the USPTO. *See* Allen Clark Zoracki, Comment: *When is an Algorithm Invented? The Need for a New Paradigm for Evaluating an Algorithm for Intellectual Property Protection.* 15 ALB. L. J. SCI. & TECH. 579, 585 n. 26 (2005).

5. Statistics from the USPTO indicate that only a very small fraction (less than 5%) of all applications claiming methods of doing business are allowed to issue. *See infra*, note 6 and accompanying text.

> however, a paradigm shift in the way PTO and the lower courts have viewed *Diehr* would engender substantial uncertainty.

(Br. of the Sol. Gen. at p. 15.)

For the past quarter-century, the Federal Circuit has taken the view, consistent with *Diehr* and predecessor cases, that there are few exceptions to § 101. One reason for this policy is that judicially created exceptions to patentable subject matter have often proven hard to administer in practice. Before the Federal Circuit's decision in *State Street*, "patent applicants often resorted to contorted claim drafting techniques in order to avoid the exclusionary rules of patent eligibility." John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U. L. REV. 771, 789 (2003). As Judge Rader remarked, pre-*State Street* law, which invoked numerous judge-made exceptions to § 101 in the field of computer software and business methods, was a "twisted knot of precedent." *Arrhythmia Research Tech. Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1061 (Fed. Cir. 1992) (Rader, J. concurring). Some commentators have likened pre-*State Street* law to the "Byzantine strands forming a Gordian knot, finding them easier to sever than to untie." Thomas, *supra*, at 789 (citations omitted). History shows that judicial exceptions to § 101 tend to create more problems than they solve. If Congress deemed it necessary, it could amend § 101, but it has left the scope of § 101 unaltered notwithstanding a debate that is far older than the statute itself.

C. Congress Has Left § 101 And Its Broad Categories Of Eligible Subject Matter Alone

The language of § 101 has remained unchanged since 1952, even in the face of decisions such as *State Street* that have confirmed the patentability of increasingly more diverse subject matter. Instead of amending § 101 to restrict the classes of eligible subject matter, Congress has passed exceptions to infringement. For example, Congress has amended 35 U.S.C. § 287, which now reads in relevant part:

> (c)(1) With respect to medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

Congress passed this provision specifically to address newly patented methods of practicing medicine, out of concern that patents on methods of practicing medicine could negatively affect public health. *See* H.R. Rep. No. 104-863, pt. 7, at § 616 (1996); *see also* Gerald J. Mossinghoff, Article, *Remedies Under Patents on Medical and Surgical Procedures*, 78 J. PATENT & TRADEMARK OFFICE SOC. 789 n. 17 (1996). Patents on novel methods of practicing medicine may prevent some doctors and hospitals from providing the best medical care known to the profession, so Congress thought it appropriate to provide medical care providers with limited protection from infringement liability. *Id.* (discussing lawsuit filed by Samuel L. Pallin against Dr. Jack A. Singer alleging infringement of U.S. Patent No. 5,080,111.) Congress specifically excluded other business entities such as

Petitioner from the protection of § 287(c)(1) by providing that the exception does not apply to "clinical laboratories services" like those at issue in this case. *See* § 287(c)(3). Congressional protection of certain actors or actions from charges of infringement is a preferable alternative to judge-created exceptions to the broad "method" category listed in § 101.

D. Broadly Patentable Subject Matter Must Still Be Novel and Non-Obvious Before a Patent Is Granted

Debate over the appropriate scope of protectable subject matter rages on, especially in the wake of the Federal Circuit's decision in *State Street*. Some see broadly patentable subject matter under § 101 as harmful to the economy because it includes methods of doing business. *See* Jay Dratler, Jr., Article: *Alice in Wonderland Meets the U.S. Patent System*, 38 AKRON L. REV. 299, 308-310 (2005). Others argue that patent incentives for inventions covering software and business methods do little to promote innovation. *See, e.g.*, Robert M. Hunt, Article: *You Can Patent That? Are Patents on Computer Programs and Business Methods Good for the Economy?*, BUSINESS REVIEW Q1 at p. 8 (Federal Reserve Bank of Philadelphia 2001) available at http://www.phil.frb.org/files/br/brq101bh.pdf (last visited on December 21, 2005). "Firms in the computer software and financial services industries were innovating rapidly long before it was thought possible to patent their innovations, yet they found effective ways to exploit their innovations without patents." *Id.* The Federal Trade Commission has also weighed in on the debate:

> The constitutional intention that patents 'promote the progress of science and useful arts' should be

> taken into account in interpreting the scope of patentable subject matter under § 101. Decision makers should ask whether granting patents on certain subject matter in fact will promote such progress or instead will hinder competition that can effectively spur innovation.

To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, a Report by the Federal Trade Commission (October 2003), available at http://www.ftc.gov/reports/index.htm (containing an index to the document in Acrobat format) (last visited December 21, 2005).

While an improvidently granted patent creates potential for economic harm, that harm is substantially outweighed by the harm that would be inflicted through judicial policy that broadly and unnecessarily restricts the scope of patentable subject matter. The risk of inappropriate patent protection is best controlled by rigorous application, on a case-by-case basis, of the other statutory requirements for patentability, §§ 102, 103, and 112. In fact, the USPTO has shown itself capable of responding to the concerns expressed by some regarding the statutory breadth of potentially protectable subject matter. Since *State Street*, the USPTO has seen a flood of applications in Class 705, which pertains to business method patent applications. *See USPTO White Paper on Automated Financial or Management Data Processing Methods (Business Methods)* (2001) available at http://www.uspto.gov/web/menu/busmethp /index.html (last visited on December 21, 2005). In response to the increased volume of such applications, the USPTO has changed its examination procedures in Class 705, requiring more robust searches for prior art, second reviews of applications, and more patent examiners. *See id.* Rigorous examination in

Class 705 has resulted in surprisingly few patents being issued in comparison to the number of filings. In 2004, just 282 patents were issued in Class 705, while some 6,200 applications were filed. *See Class 705 Application Filing and Patents Issue Data* (October 31, 2004) available at http://www.uspto.gov/web/menu/pbmethod/ applicationfiling.htm (last visited December 21, 2005).[6] In light of these statistics, the alarm sounded by some in the wake of *State Street* seems unjustified. *See, e.g.*, Dratler, *supra*, at 308-310.

Rigorous examination focused on §§ 102, 103, and 112 is the most practical and economically sensible way to prevent the issuance of inappropriate patents. By contrast, broadly restricting patentable subject matter in an effort to eliminate improvidently granted patents could well do greater economic harm. Any further judicially created restrictions on the scope of § 101 would inevitably create uncertainty and would likely result in numerous challenges to existing patents, thereby disturbing many economic actors' reasonable reliance on what was previously thought to be well-settled law. Indeed, such restrictions might well impair incentives for innovation in inherently risky technology-based industries.

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6. There is typically a delay of thirty-six months to the first Office Action on the merits of applications filed in Class 705, and a forty-two-month average disposal time with an application moving to issue or abandonment. In 2000, there were 7,800 applications filed in Class 705 and in 2001 there were 8,700 applications filed in Class 705. *See Application Filing Data, supra.*

CONCLUSION

For the reasons set forth above, the petition should be dismissed as improvidently granted. In the alternative, if the Court decides to address the § 101 issue, the FCBA respectfully urges the Court not to depart from or expand upon its own long-established precedent and to confine its ruling to the facts of this case.

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